

REMARKS

By this amendment, Applicant amends claims 1, 3, 5, 7, 9, 12, and 15 and cancels claims 2, 4, 6, 8, 10, 11, 13, 14, 16, and 17. No new matter is added by this amendment. Claims remaining in this application are:

Independent claims: 1, 18, 20

Dependent claims: 3, 5, 7, 9, 12, 15, 19, 21

Amended claim 1 recites a wound treatment composition that includes a combination of one or more antimicrobial agents selected from the group of Polymyxin B Sulfate, Bacitracin Zinc, and 8—Hydroxyquinoline Sulfate, Phenylephrine HCL, micronized Hydrocortisone, Povidone-Iodine, Benzoin, Ichthammol, and a base ointment including anhydrous lanolin and white petrolatum. As noted by Examiner in the office action, the cited art fails to disclose the combination of claim 1.

One of the problems of the prior art which, in some of the references is explicitly acknowledged and utilized, is the instability of prior art wound compositions. For example, Battaglia specifically claims the use of a volatile solvent. See Battaglia, ¶ 0015. As Examiner can appreciate, a volatile solvent would make the compound of Battaglia inherently unstable and Battaglia acknowledges that his compound would dry on the skin. See *id.* Similarly, Crawford recites an aqueous solution which would inherently change through evaporation, thereby causing the proportions of the compound and their effects to change prior to, and during, use. Crawford, col. 1, ll. 35–38.

The approach of Burks (see Burks, p. 213) and Mooney (see Mooney, FIG. 6) is to incorporate these volatile compounds into wound dressings. However, as Examiner may

appreciate, this would not stabilize the compounds but would rather hold the composition in place as long as possible before they change, e.g. evaporate or otherwise alter.

Applicant submits that, in the recited composition, the composition and its constituent parts are stabilized. Moreover, the process of forming the composition maintains the stability during the formation. As acknowledged by Examiner, the cited references, alone or in combination, fail to disclose (a) the recited combination recited in claim 1, (b) the specific proportions recited in claim 18, and (c) the process of manufacturing a composition recited in claim 20.

Specifically, referring to amended claim 1, none of the cited references discloses or suggests using the recited combination. Crawford discloses using an aqueous solution incorporating Ichthammol which, as Examiner would readily acknowledge, would change through evaporation of the water in the aqueous solution after the compound is applied to the skin. As such, Crawford fails to disclose a stable composition and, in fact, teaches away from a composition that maintains its stability during use. While Battaglia identifies the desirability of using tincture of Benzoin, Battaglia specifically identifies the use of a volatile solvent intended to allow the composition to “dry[] on the skin.” Battaglia, ¶ 0015. As such, Battaglia fails to disclose a composition that maintains its stability during use and, in fact, teaches away from combination with compositions that maintain stability during use. Burks identifies the use of Povidone-Iodine solution but only discloses the use of the solution to either incorporate into wound dressings or topically **irrigate** the wound. Thus, Burks also teaches away from combination in a composition that maintains stability during use. Similarly, Mooney discloses the use of antimicrobial and anti-inflammatory agents as a wound treatment. However, Mooney

stabilizes the agents through incorporating the agents into a dressing. Again, Mooney fails to disclose or suggest stabilizing the antimicrobial and anti-inflammatory agents by combining them with other agents as recited in amended claim 1.

As Examiner is aware, if a proposed modification of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the reference are insufficient to render the claims prima facie obvious. M.P.E.P. section 2143.01. Crawford specifically teaches an aqueous solution which would inherently change through evaporation after application; Battaglia specifically teaches the use of a volatile solvent to allow “drying on the skin;” Burks specifically teaches the use of a solution to treat a dressing or topically irrigate a wound; and Mooney specifically teaches the incorporation of agents into a dressing. To modify Battaglia and Burks as Examiner suggested would expressly change the principle of operation of the references. Similarly, using a carrier with an **anhydrous** component (anhydrous lanolin) as recited in the claim would change the principle of operation of Crawford’s **aqueous** solution. To stabilize the agent disclosed in Battaglia would expressly prevent “drying on the skin” as taught by Battaglia. Similarly, to stabilize the agent disclosed in Burks would expressly alter the methods of application taught by Burks. To stabilize the agent disclosed in Mooney would expressly avoid the incorporation of the agent into a wound dressing as taught by Mooney. As such, Applicant submits that these references cannot be modified and/or combined with other references as suggested by Examiner and, as such, fail to render obvious the recited invention. Therefore, Applicant submits that amended claim 1 is allowable over the cited references.

Referring to claim 18, none of the cited references discloses or suggests using the

claimed proportions. As argued above with respect to claim 1, Applicant submits that the compositions disclosed in Crawford, Battaglia, Burks, and Mooney cannot be modified or combined with other compositions recited in amended claim 18 because that would alter the disclosed principle of operation, i.e. through an “aqueous solution,” “drying on the skin,” incorporation into a dressing or topical irrigation, and incorporation into a dressing, respectively. As such, Applicant submits that amended claim 18 is allowable over the cited references.

Additionally, Examiner suggests that the specific proportions recited in claim 18 would be obvious to one of ordinary skill in the art. However, Applicant submits that, even after the recent change to obviousness analysis, Examiner must still provide the reasoning for suggested change or combination. Applicant respectfully submits that Examiner will be unable to do so. For example, Armstrong discloses the use of Phenylephrine in combination with an “inert carrier.” Armstrong fails to disclose or suggest other active ingredients and, as such, teaches away from the combination recited in the claim. More particularly, Armstrong fails to disclose the use of other compositions in combination with the recited agent to provide additional therapeutic effects. That is, Armstrong has as its sole purpose stopping bleeding through vasoconstriction. However, Armstrong fails to acknowledge that some blood flow may be desirable to encourage healing and reduce the chances of infection. While Armstrong discloses a wide range of percentage concentrations of Phenylephrine, Armstrong fails to disclose or suggest a composition with a low proportion of Phenylephrine **in combination** with other agents to encourage healing and discourage infection. That is, because Armstrong only discloses compositions with Phenylephrine and an inert carrier, Armstrong fails to disclose or suggest and, in fact, teaches away from, a composition in which Phenylephrine is only a minor player in an

overall synergistic composition. Therefore, in addition to the arguments presented above for the inapplicability of Crawford, Burks, Battaglia, and Mooney, Applicant submits that Armstrong is, likewise, inapplicable to claim 18. Therefore, Applicant submits that claim 18 is allowable over the cited references.

Referring to claim 20, the cited art fails to disclose the use of an anhydrous lanolin and white petrolatum in a base ointment to incorporate the liquid compounds in the composition and maintain the consistency of the final product. Again, as argued above with respect to claims 1 and 18, the cited references fail to disclose a composition that is (a) stable and (b) includes multiple agents working in synergy. Since none of the references disclose a stable, synergistic combination, none of the references can disclose a method for producing a stable, synergistic combination as recited in claim 20. Specifically, Applicant submits that claim 20 is allowable because none of the references specifically discloses the use of an anhydrous lanolin to incorporate and liquid agents and provide a consistent composition. As discussed above, Battaglia specifically discloses a process of manufacture using a volatile solvent which would dry on the skin and Burks specifically discloses a process of manufacture using an aqueous solution, both of which are exactly opposite to the process of manufacture recited in claim 20 in which a stable (rather than volatile) anhydrous (rather than aqueous) lanolin is used. As such, Battaglia and Burks specifically teach away from the process of manufacture recited in claim 20.

Similarly, while Merck discloses the physical characteristics of 8—Hydroxyquinoline Sulfate, it specifically discloses that the agent is soluble in water, glycerol (to a lesser extent), and alcohol (to a small extent). However, it does not disclose the combination of 8—Hydroxyquinoline Sulfate with an anhydrous agent, such as anhydrous lanolin, and a

hydrophobic agent, such as white petrolatum. Again, Merck specifically requires the use of water, alcohol, or a **hydrophilic** solvent such as glycerol and, as such, specifically teaches away from a combination with an **anhydrous** and/or **hydrophobic** agent. Since Merck teaches away from a combination of 8—Hydroxyquinoline Sulfate in the manner recited in claims 1, 18, and 20, Applicant submits that the Merck fails to disclose or suggest the present invention. For this reason, and for the reasons advanced above with respect to claims 1 and 18, Applicant submits that claim 20 is allowable over the cited references.

Claims 3, 5, 7, 9, 12, and 15 depend from claim 1 and recite specific proportions of agents recited in claim 1. Because these claims depend from allowable claim 1, and for the reasons advanced with respect to claims 1, 18, and 20 with respect to the specific combination recited and the proportions recited, Applicant submits that claims 3, 5, 7, 9, 12, and 15 are allowable over the cited references.

Claim 19 depends from claim 18 and recites a composition of the base ointment. Because this claim depends from allowable claim 18, and for the reasons advanced with respect to claims 1 and 20 regarding the failure of the prior art to disclose a stable, anhydrous, hydrophobic base ointment in combination with the active ingredients recited in claim 18, Applicant submits that claim 19 is allowable over the cited references.

Claim 21 depends from claim 20 and recites a product-by-process of claim 20. For the reasons advanced with respect to claims 1 and 18, and because claim 21 depends from allowable claim 20, Applicant submits that claim 21 is allowable.

#### Conclusion

For the reasons advanced above, all pending claims are now believed to be in condition

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for allowance. Should Examiner believe that a telephone interview would advance the prosecution of this application, the undersigned would invite and request such an interview.

Respectfully submitted,  
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